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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,962	08/22/2003	David Farrar	PT-2683-US-NP	8400

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EXAMINER	
STROUD, JONATHAN R	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
08/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,962	FARRAR ET AL.	
	Examiner	Art Unit	
	JONATHAN R. STROUD	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/07/2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58–84* is/are pending in the application.

4a) Of the above claim(s) *61, 64, 65, 70, 77–83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58–60, 62, 63, 66–69 and 71–76, and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :02/24/2011, 02/25/2011, 02/24/2011.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 06/07/2011 have been fully considered but they are not persuasive. To the extent that they are not mooted by the amendment to the claims and the subsequent shift in position taken by the office (prompted only by the amendments to the claims), they are addressed here, and are not persuasive.

Applicant first argues that the King reference does not teach tissue-fixation devices which are "substantially non-porous prior to implantation."

This is not found persuasive, as King discloses a number of means of injecting, molding, and attempting to solidify the implant so that, as it is implanted, it is substantially non-porous prior to implantation. Indeed, that is the primary goal of the King reference - to create a structurally reinforced solid device implant with biobeneficial properties. The King reference discusses how the ceramic alone can be brittle and discloses methods which would substantially (if not entirely) render the device non-porous, particularly in the "interconnected pore," "open-cell" embodiments. *See* para. [0024].

Applicant second argues that the prior art King also does not teach bone plugs or materials where the polymer is injected "into and around each plug" to form a "layer of polymers that cover the surface of the devices." Applicant points to the fact that the King reference teaches that the King devices *may* be fabricated by compression

molding where the polymer is injected *into* the matrix as evidence that no external polymer layer is formed that might 'substantially' cover the device.

True enough; but the King reference also disclosed a number of other methods of manufacture, many of which involve simply immersing the ceramic in a liquid polymer and allowing infiltration. *See* pars. [0060–65] (outlining "transfer molding," "flow molding," and other varying methods of manufacture). Inherently, any device mold which is then covered in a liquid or viscous flow of polymer (that is then allowed to infiltrate and set) would be substantially covered.

Furthermore, the scope of 'substantially covered' is thrown into question by the fact that it appears to be unsupported by the prior specification. Applicant is allowed to be his own lexiconographer, but without a specific definition disclosed in the application as originally filed, it is difficult to determine the scope of the limitation, and so must be broadly construed; a reasonable interpretation is one where the majority of a porous surface exposes a polymer.

Applicant third argues that the Beam reference does not teach an outer polymer layer on the outside of the device, substantially covering the ceramic aspect. This is flatly contradicted by, for instance, Fig. 15, which shows element 1620, a coating of polymer, over the entire ceramic structure. Thus, applicant's arguments are unpersuasive.

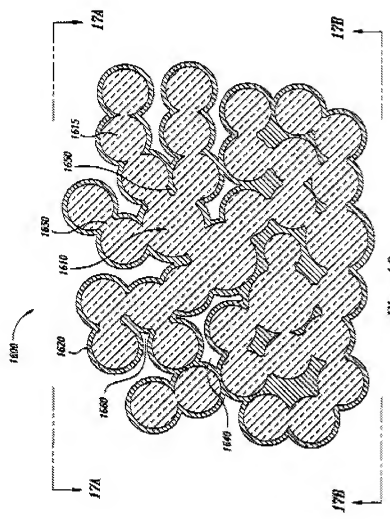

Fig. 16

Applicant fourth argues that the Brown reference (which prima facie shows a polymer layer covering the *entirety* of the ceramic layer, see fig. 1, reproduced below) is non-analogous art under KSR because the purposes of Brown's "porous layers" are to facilitate nutrient transport and cell invasion, and that the scaffolds and polymers must be porous prior to the time of implantation.

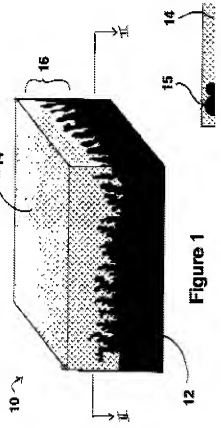

Figure 1

Applicant's arguments are persuasive. As amended, the claim recites clearly a "non-porous" first and second layer, and to the extent that Brown is a relevant reference for other reasons, it does not teach non-porous, but rather, porous materials. This rejection has thus been withdrawn. The reference might be of relevance, however, for the teaching of an entire layer of applied ceramic disposed overtop of a layer of polymer, and so it at least relevant to the prosecution of this case.

Claim Objections

Claim 84 is objected to because of the following informalities: it is grammatrically incorrect, and should read "is 0.050 inch*es* in thickness." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 56, as amended, is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims that the device now "substantially covers" the surface. However, the limitation does not appear in the specification as originally filed, and so there is no support in the application as initially filed. Furthermore, it is unclear what the limiting scope of a "substantial[[cover" would be. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58–60, 62, 63, 66 and 69–76 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Publication to King *et al*, 2004/0002770.

Re claim 58, King discloses a polymer-bioceramic structure used to repair bone defects, which comprise a polymer disposed in a porous bioceramic matrix.

Re claim 59, the pore size is about 100 to about 1000 microns.

Re claim 60, King discloses that the void volume should be about 80, 50, or 70 of volume, para. 0013; likewise King discloses using a commercially available scaffold that has a porosity of 90%, para. 0027. *See also* para. 0037 ("interstices, pockets, channels, passages, tunnels, and the like comprise less than 50% of the volume possessed by the porous bioceramic matrix.")

Re claim 62, King discloses a first bioceramic component.

Re claim 63, King discloses the other component can be a strengthening polymer material.

Re claim 66, King discloses a first component is a bioceramic and a second is a polymer.

Re claim 69, King discloses filling the structure with bioactive substances or drugs, abstract.

Re claim 70, King discloses bioresorbable polymers, para. 0012, 0028.

Re claim 71, King discloses collagen, para. 0032

Re claim 72, King discloses glycolides, para. 0029.

Re claim 73, King discloses block copolymers made of blends of glycolic acid and trimethylene carbonate, i.e., Polyglyconate B (aka Maxon TM), *see* claim 15, and further discloses using tricalcium phosphate as the bioceramic material, para. 0010.

Re claim 74, King disclose polylactic acid (PLA), para. 0010, and hydroxyapatite, para. 0023.

Re claim 75, King discloses monomers forming the polymers.

Re claim 76, King discloses monomers such as cyclic esters, para. 0031.

Claims 58–60, 62–63, 66, 70–74 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent to Beam *et al* 7,122,057.

Re claim 58, Beam discloses creating a porous pre-formed "engineered regenerative biostructure" (erb) for implantation into a human body as a bone substitute, and discloses it be porous, abstract.

Beam further discloses filling the interstitial porous places with a polymer material, "infused as a monomer and then polymerized," col. 21 ll. 65-68; *see also* col. 22 ll. 10-20 ("The final biostructure could have essentially all of its empty spaces filled, or it could still have empty spaces.")

Re claim 59, for varying pore sizes see fig. 22.

Re claim 60, likewise, Beam discloses the entire range of pore sizes disclosed in fig. 22 which correspond to a wide range of interstitial volumes.

Re claim 62, as just explained, Beam discloses a first ceramic material and a polymer filler material.

Re claim 63, Beam discloses the other component can be a strengthening polymer material, as explained above.

Re claim 66, Beam discloses the first component is ceramic and the second polymer.

Re claim 69, Beam discloses filling the structure with "bioactive substances," col. 22 ll. 5–20.

Re claim 70, Beam discloses the polymers (as follows) are bioabsorbable.

Re claim 71, Beam discloses polymers in the genus at Col. 18 ll. 65–68, col. 19 ll. 1.

Re claim 72, Beam discloses polymers in the genus at Col. 18 ll. 25-35.

Re claims 73 and 74, Beam discloses hydroxyapatite and tricalcium phosphate, col. 18 ll. 20–22, and gl;ycolic acid, trimethylene carbonate, and polylactic acid, see cols. 18 & 19, ll. 55–68 & 1–35.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 67 and 68 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication to King *et al*, 2004/0002770, or to Beam *et al* 7,122,057.

Re claims 67 and 68, the rate of degradation is disclosed (in King) is a results-effective variable and would be advantageously altered.

> It is contemplated that ***the rate of biodegradation, bioerosion, or bioresorption of the polymer component of the structures described herein***, or the rate of release of bioactive agents incorporated in the structures described herein ***may be controlled by varying either the type of or molecular weight of the polymer or copolymer components***, by including a release rate modification agent, or by varying the combination and concentrations of ingredients that comprise the polymer itself.
>
> . . . In certain embodiments, it is appreciated that a perimeter that resorbs rapidly and allows rapid infiltration of bone ingrowth at the perimeter relative to the interior ***may be desirable.***
>
> Para. 0034–35; 0037.

Further, King and Beam, all disclose numerous polymers and ceramics with varying rates of degradation and selecting them based on varying the rates in degradation; and various combinations which would fall well within the ranges disclosed.

Re claim 84, the thickness of any external layer of polymer is not explicitly disclosed.

However, King and Beam both disclose varying the injection and orientation as needed: for instance, King discloses, para. [0034]:

> [0034] It is contemplated that the rate of biodegradation, bioerosion, or bioresorption of the polymer component of the structures described herein, or the rate of release of bioactive agents incorporated in the structures described herein may be controlled by varying either the type of or molecular weight of the polymer or copolymer components, by including a release rate modification agent, or by varying the combination and concentrations of ingredients that comprise the polymer itself. For example, poly(lactic acid)-based polymers typically undergo resorption at rates slower than poly(glycolic acid)-based polymers. Resorption rates may be manipulated by choice of the ratio of the mixture of such polymer components. ***Furthermore, the polymer may be disposed in the structure in a radially varying manner, such that resorption characteristics vary from the center of the structure to the perimeter***

> ***of the structure. In certain embodiments, it is appreciated that a perimeter that resorbes rapidly and allows rapid infiltration of bone ingrowth at the perimeter relative to the interior may be desirable.*** Such configurations may be fabricated as described herein by varying the polymer component, such as by varying the polymer molecular weight distribution or polymer, copolymer, or polymer blend composition as a function of cross-section of the structure.

King thus discloses the desirability of varying the amount, composition, and orientation of any polymer component. Beam likewise discloses a wide variety of thicknesses, layer sizes, and the desirability of variability.

The optimization within prior art conditions is obvious to one of ordinary skill in the art. See MPEP 2144.05. Further, the selection of a material or equivalent recognized in the prior art supports a prima facie case of obviousness. See MPEP 2144.05 II.A.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the choices of materials laid out in King, Brown, or Beam, or to select some of the material combinations disclosed, which would produce differentials in degradation within the ranges disclosed, and also because King teaches those are results-effective variables which are well within one of ordinary skill in the arts' skill to optimize. *See* MPEP 2144.05 II.A.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Stroud, whose telephone number is (571) 270-3070. The examiner can normally be reached Monday through Thursday from 11am to 8:30pm.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, David Isabella, at 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner by phone, you may send an email inquiry to jonathan.stroud@uspto.gov; if that is unsuccessful, you may contact TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JONATHAN STROUD/
Examiner, Art Unit 3774

/THOMAS J SWEET/
Supervisory Patent Examiner, Art Unit 3738